K103536

stryker

Medical

510(k) Summary

DEC 16 2010

Manufacturer and Submitter

Company Name:	Stryker Corporation, Medical Division
Company Address:	3800 E. Centre Ave. Portage, MI 49002 phone: 269.324.6689 fax: 269.329.2307
Contact Person:	Renata Sila
Date Summary Prepared:	November 4, 2010

Device

Trade/Device Name:	iBed™ Wireless with iBed™ Awareness
Common/Usual Name:	Accessory to AC-Powered Adjustable Hospital Bed
Classification Name:	AC-Powered Adjustable Hospital Bed
Regulation Number:	21 CFR 880.5100
Product Code:	FNL
Classification Panel:	General Hospital
Classification:	Class II

Predicate Devices:

Advance Series from Hill-Rom, Hill-Rom (K922352)
VivaTRAK™, Wireless MedCARE, LLC (K101109)

Device Description

The iBed™ Awareness is used to monitor hospital bed status and to assist the Healthcare Provider in providing patient care. The system is integrated into Stryker hospital bed to monitor bed information such as: iBed™ Awareness status, bed exit status, siderail status, bed brake status, fowler angle, and weight on bed, for example. The Healthcare Professional can set the alerting function (audible and lights) to activate if bed status has changed. The iBed™ Wireless device is a tool that facilitates the wireless transmission of the bed status data using a wireless hardware and software device to the hospital server. The data can be captured by hospital data collection systems (developed and provided by Third Parties; not part of this submission). Through the use of the third party software, the data may be displayed at user-defined locations, such as nursing stations.

Intended Use/Indications for Use

The intended use for the iBed™ Wireless (with iBed™ Awareness) is to assist clinical staff to monitor bed parameters on specific Stryker beds. The desired bed parameters will be set by clinicians at the bedside. The iBed™ Wireless software is intended to be used only with specifically enabled Stryker beds that have been verified and validated with the iBed™ Wireless software, and is not intended to provide bed status information

for non-Stryker beds. The iBed™ Wireless software is not intended to communicate any patient status information, nor to permanently store any type of data. The iBed™ Wireless with iBed™ Awareness System is not intended to provide automated treatment decisions or as a substitute for professional healthcare judgment. The iBed™ Wireless with iBed™ Awareness System is not a replacement or substitute for vital signs monitoring or alert equipment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate health care professional.

Substantial Equivalence Analysis

The iBed™ Wireless with iBed™ Awareness is similar in technology and intended use to the AC-Powered Hospital bed Advance Series from Hill-Rom, Hill-Rom (K922352), and the VivaTRAK™, Wireless MedCARE, LLC (K101109), which monitors in-bed activity using wireless technology.

The slight difference in Intended Use statements between the iBed™ Wireless with iBed™ Awareness and the predicates include that the VivaTRAK™ system uses include the Electronic Health Record (EHR) application interface, while iBed Wireless™ system does not, and the type of data transmitted with iBed Wireless includes other bed parameters in addition to the in-bed activity (bed exit status) monitored with VivaTRAK™. These differences do not impact safety or effectiveness of the device when used as labeled, as the device has been fully tested for use and performance to demonstrate its safe and effective use. Neither the iBed™ Wireless with iBed™ Awareness nor the VivaTRAK™ devices are intended to provide automated treatment decisions or be used as a substitute for professional healthcare judgement.

Non-Clinical Performance Summary

Stryker Medical has verified and validated that the iBed™ Wireless with iBed™ Awareness meets its functional, performance, safety and efficacy specifications and requirements. Software testing and hardware testing of each component and of the final device have been conducted extensively. The device has been tested according to International Standards for compliance with:

- Software module and system-wide validation and verification testing according to ANSI/AAMI/IEC 62304,
- Electrical safety and life cycle testing according to IEC 60601-1, and IEC 60601-2-38,
- Electromagnetic safety and emissions, and electromagnetic compatibility testing according to IEC 60601-2, and
- Standards for information technology, IEEE 802.11.

The extensive performance testing that has been conducted on the individual components and on the finished system demonstrate that the iBed™ Wireless with iBed™ Awareness are safe and effective, and perform as well or better than the predicate devices.

Conclusions

In summary, Stryker Corporation, Medical Division believes that the iBed™ Wireless with iBed™ Awareness is as safe and effective as similar devices currently on the market, and concludes that the iBed™ Wireless with iBed™ Awareness is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
C/O Mr. William Sammons
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

DEC 16 2010

Re: K103536
Trade/Device Name: iBed™ Wireless with iBed™ Awareness
Regulation Number: 21 CFR 880.5100
Regulation Name: AC-Powered Adjustable Hospital Bed
Regulatory Class: II
Product Code: FNL
Dated: November 30, 2010
Received: December 1, 2010

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

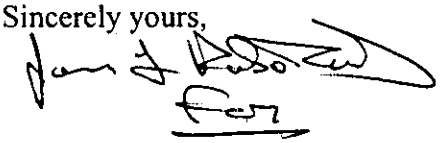
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 16 2010

510(k) Number (if known): K103536

Device Name: iBed™ Wireless with iBed™ Awareness

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 12/6/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103536